

**PROPRIETARY MATERIAL NOT OPEN TO PUBLIC.  
TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED PATENT AND  
TRADEMARK OFFICE EMPLOYEE**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Attorney Docket No.: 38777-0059

Applicant(s): Milan S. BLAKE *et al.*

Serial No.: To be assigned                      Examiner: To be assigned

Filing Date: October 3, 2003                      Group Art Unit: To be assigned

Title: IMPROVED METHOD FOR THE PRODUCTION OF BACTERIAL  
TOXINS

**PROPRIETARY INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and MPEP §724**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following is a listing of a co-pending U.S. patent application:

| <b>SERIAL NO./<br/>FILING DATE</b> | <b>TITLE</b>                                  |
|------------------------------------|---|
| 09/825,769<br>April 4, 2001        | METHOD FOR THE PRODUCTION OF BACTERIAL TOXINS |

Applicants consider the aforementioned documents and the disclosure of its existence as pending applications to constitute proprietary information. Accompanying this Proprietary Information Disclosure Statement is a transmittal letter indicating that the materials contained herein are proprietary, as required by MPEP §724.02.

Applicants respectfully request that the Examiner consider the foregoing information and provide in the next official communication the information set forth in MPEP §724.04(a), particularly the information under item (C), so that the Applicants

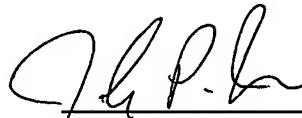
can, if appropriate, subsequently file a petition to expunge those materials, as provided according to MPEP §724.05.

This Proprietary Information Disclosure Statement is being filed under the provisions of 37 C.F.R. § 1.97(b) before the mailing of a first Office Action on the merits, therefore, no fee is due. However, in the event that the USPTO determines that a fee is due for the filing of this document, the Commissioner is hereby authorized to charge any such fee to Deposit Account No. 08-1641.

Respectfully submitted,

October 3, 2003  
Date

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Attorney for Applicant  
Registration No. 33,715

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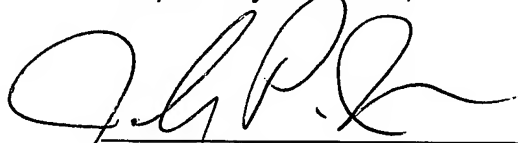
**TRANSMITTAL LETTER FOR  
PROPRIETARY INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and MPEP §724**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Attached hereto is a Proprietary Information Disclosure Statement submitting proprietary information to the Patent and Trademark Office in accordance with the requirements of 37 C.F.R. §1.56 and MPEP §724. Applicants respectfully request that the information be considered only by the Examiner in charge of the above-captioned application, or other authorized Patent and Trademark Office employee.

Respectfully submitted,



John P. Isacson  
Attorney for Applicant  
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October 3, 2003  
Date

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Attorney Docket No.: 38777-0059

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Serial No.: To be assigned

Examiner: To be assigned

Filing Date: October 3, 2003

Group Art Unit: To be assigned

Title: IMPROVED METHOD FOR THE PRODUCTION OF BACTERIAL  
TOXINS

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

Applicants believe that the instant Information Disclosure Statement is being filed within three months of the filing date under 37 CFR §1.97(b)(1), therefore, no fee is required in connection with its filing.

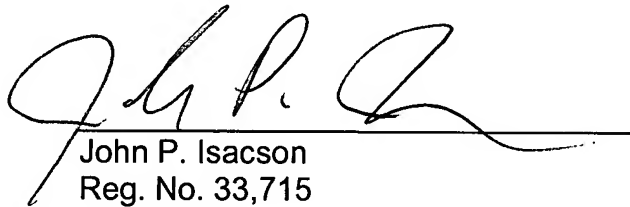
Applicants submit herewith on Form PTO/SB/08A, a listing of the documents cited by or submitted to the Patent Office in parent application Serial No. 09/825,770, filed April 4, 2001. The relevance of these prior art documents is explained in the parent application.

As provided in 37 C.F.R. §1.98(d), copies of the documents are not being provided since they were previously cited by or submitted to the Patent Office in parent application Serial No. 09/825,770 filed April 4, 2001.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

October 3, 2003  
Date

  
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|   |                    |                 |   |  |          |                                     |  |
|---|--------------------|-----------------|---|--|----------|-------------------------------------|--|
| Sheet 1 of 1<br>Form PTO/SB/08A   |                    |                 |   | ATTY DOCKET NO.<br><b>38777-0059</b>         |          | SERIAL NO.<br><b>To be assigned</b> |  |
| <b>LIST OF REFERENCES CITED<br/>BY APPLICANT(S)</b>                             |                    |                 |   | APPLICANT(S)<br><b>Milan S. BLAKE et al.</b> |          |                                     |  |
| Date Submitted: <b>October 3, 2003</b>  |                    |                 |   | FILING DATE<br><b>October 3, 2003</b>        |          | GROUP<br><b>To be assigned</b>      |  |
| <b>U.S. PATENT DOCUMENTS</b>  |                    |                 |   |  |          |                                     |  |
| *EXAMINER<br>INITIAL  | DOCUMENT<br>NUMBER | DATE<br>(M/D/Y) | NAME  | CLASS  | SUBCLASS | FILING DATE IF<br>APPROPRIATE       |  |
|   | A01                | 5,614,396       | 3/25/97   | Bradley et al.                               |          |                                     |  |
|   | A02                | 5,789,215       | 8/4/98  | Berns et al.                                 |          |                                     |  |
|   | A03                | 4,950,599       | 8/21/90   | Bertling                                     |          |                                     |  |
|   | A04                | 5,460,941       | 10/24/95  | Camerini-Otero et al.                        |          |                                     |  |
|   | A05                | 6,031,149       | 2/29/00   | Chambon et al.                               |          |                                     |  |
|   | A06                | 5,272,071       | 12/21/93  | Chappel                                      |          |                                     |  |
|   | A07                | 5,777,195       | 7/7/98  | Fienberg et al.                              |          |                                     |  |
|   | A08                | 5,612,205       | 3/18/97   | Kay et al.                                   |          |                                     |  |
|   | A09                | 6,015,676       | 1/18/00   | Lin et al.                                   |          |                                     |  |
|   | A10                | 5,616,491       | 4/1/97  | Mak et al.                                   |          |                                     |  |
|   | A11                | 5,557,032       | 9/17/96   | Mak  |          |                                     |  |
|   | A12                | 5,948,653       | 9/7/99  | Pati et al.                                  |          |                                     |  |
|   | A13                | 5,965,443       | 10/12/99  | Reznikoff et al.                             |          |                                     |  |
|   | A14                | 4,965,205       | 10/90   | Quentin-Millet et al.                        |          |                                     |  |
|   | A15                | 5,338,670       | 8/16/94   | Sekura et al.                                |          |                                     |  |
| <b>FOREIGN PATENT DOCUMENTS</b>   |                    |                 |   |  |          |                                     |  |
|   | DOCUMENT<br>NUMBER | DATE<br>(M/D/Y) | COUNTRY   | CLASS  | SUBCLASS | TRANSLATION<br>YES NO               |  |
|   |                    |                 |   |  |          |                                     |  |
|   |                    |                 |   |  |          |                                     |  |
| <b>OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)</b> |                    |                 |   |  |          |                                     |  |
|   | A16                | Andresen        | FEMS Immunology and Medical Microbiology 23: 295-301 (1999) |  |          |                                     |  |
|   | A17                | Frohlich et al. | Journal of Biotechnology 39: 205-219 (1995)                 |  |          |                                     |  |
|   |                    |                 |   |  |          |                                     |  |
| EXAMINER  |                    |                 |   | DATE CONSIDERED                              |          |                                     |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.